



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,509	03/24/2000	Zenoviy Tkachuk	000152	2421

23850 7590 07/18/2003

ARMSTRONG, WESTERMAN & HATTORI, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/534,509

Applicant(s)
Zenoviy Tkachuk

Examiner
Shin-Lin Chen

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 17, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-12, 20-23, 25-32, and 34-45 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5, 10-12, 23, 25-32, 34-37, and 39-42 is/are allowed.
- 6) ☒ Claim(s) 6, 8, 9, 20-22, 38, and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1633

DETAILED ACTION

Applicant's amendment filed 6-17-03 has been entered. Upon further consideration, the finality of the Official action mailed 7-9-02 (Paper No. 14) has been withdrawn. Claims 1, 13-19, 24, 33 and 46-55 have been canceled. Claims 6, 8-12, 20-23, 25-32 and 34-42 have been amended. Claims 2-6, 8-12, 20-23, 25-32 and 34-45 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 has been amended to read on a method of stabilizing acid-challenged erythrocyte membranes of a mammal by administering yeast total RNA in an amount within a range from 0.1mg to 1g per kg weight of a mammal to said mammal and such subject matter is considered new matter. The specification fails to provide sufficient description to support administering yeast total RNA in an amount within a range from **0.1mg to 1g per kg weight** to a mammal to stabilize acid-challenged erythrocyte membranes of a mammal.

Art Unit: 1633

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 20-22, 38 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayukawa et al., 1971 (US Patent 3,615,654) in view of Robbins et al., 1975 (US Patent 3,914,450).

Claims 20-22, 38 and 43-45 are directed to a pharmaceutical composition comprising total yeast ribonucleic acid and a pharmaceutically acceptable vehicle, carrier, or diluent, wherein said ribonucleic acid comprises more than 14.5%, 15.16%, or 15.49% nitrogen and comprises more than 8.6%, 9.0% or 9.05% phosphorous contents.

Ayukawa teaches preparation of yeast ribonucleic acid from torula yeast and said yeast ribonucleic acid contains 8.5% phosphorous and 15.1% nitrogen contents (column 6, 7). The term "pharmaceutical" does not carry weight in 103(a) rejection. The solution, such as ethanol solution, containing the yeast ribonucleic acid is considered a pharmaceutical acceptable vehicle, carrier, or diluent.

Ayukawa does not specifically teach phosphorous content that is higher than 8.5% or nitrogen content that is higher than 15.1%.

Art Unit: 1633

Robbins teaches determination of RNA content from yeast cells and "The nucleic acid is considered to contain 16.3% nitrogen. Therefore, the RNA content divided by 6.13 gives the nitrogen content of the nucleic acid" (column 4, lines 40-42).

It would have been obvious for one of ordinary skill at the time of the invention to prepare yeast ribonucleic acid having nitrogen content of more than 15.16% or 15.49% and having phosphorous content of more than 8.6%, 9.0% or 9.05% because Ayukawa teaches preparation of yeast ribonucleic acid containing 8.5% phosphorous and 15.1% nitrogen contents and Robbins teaches that the nucleic acid is considered to contain 16.3% nitrogen, which is higher than 15.16% or 15.49%. Further, the nucleotides of ribonucleic acid contain both nitrogen and phosphorous, therefore, the phosphorous content of ribonucleic acid is proportional to its nitrogen content. Since Robbins teaches that the nucleic acid is considered to contain 16.3% nitrogen, it would be obvious for one of ordinary skill at the time of the invention to prepare yeast ribonucleic acid having phosphorous content of more than 8.6%, 9.0% or 9.05%. Thus, it would have been obvious for one of ordinary skill to practice the claimed invention with reasonable expectation of success because of the teachings of Ayukawa and Robbins.

Conclusion

Claims 6, 8, 9, 20-22, 38 and 43-45 are rejected. Claims 2-5, 10-12, 23, 25-32, 34-37 and 39-42 are in condition for allowance.

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'S. Chen'.

Shin-Lin Chen, Ph.D.